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Atty. Dkt. No. 310473-1250

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Guy Michael MILLER, et al.

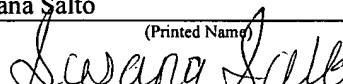
Title: METHODS FOR THE
PREVENTION AND
TREATMENT OF CEREBRAL
ISCHEMIA USING NON-ALPHA
TOCOPHEROLS

Appl. No.: 10/020,450

Filing Date: 12/14/2001

Examiner: Spivack, Phyllis G.

Art Unit: 1614

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EXTENSION FEE TOTAL:		\$120.00
CLAIMS, EXTENSION AND DISCLAIMER FEE TOTAL:		\$120.00
[X]	Small Entity Fees Apply (subtract ½ of above):	\$60.00
11/28/2005 DTESEM1 00000041 10020450	TOTAL FEE:	\$60.00
01 FC:2251	60.00 OP	

[X] Check No. 1454 in the amount of \$310.00 is enclosed for the one-month Extension of Time fee, \$60.00, and the Appeal Brief fee, \$250.00.

Atty. Dkt. No. 310473-1250

[X] The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date Nov. 23, 2005

By L.L.T.

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Atty. Dkt. No. 310473-1250

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant: Guy Michael MILLER, et al.

Title: METHODS FOR THE
PREVENTION AND
TREATMENT OF CEREBRAL
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EV 643 730 944 US (Express Mail Label Number)	November 23, 2005 (Date of Deposit)
Susana Salto (Printed Name)	
(Signature)	

APPEAL BRIEF

Mail Stop Appeal Brief – Patents
P.O. Box 1450
Alexandria, VA 22313-1450
11/28/2005 DTESEM1 00000041 10020450
02 FC:2402 250.00 OP

Sir:

Under the provisions of 37 C.F.R. §41.37, this Appeal Brief is being filed together with a check in the amount of \$250.00 covering the 37 C.F.R. §41.20(b)(2) appeal fee for a small entity. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 50-0872. This Appeal Brief is timely filed, together with a one-month extension of time on or before the due date of December 8, 2005.

REAL PARTY IN INTEREST

The real party in interest in this application is Galileo Pharmaceuticals, Inc., assignee of the entire right, title, and interest to this application by virtue of an assignment from the six of seven inventors to Galileo Laboratories, Inc. which assignment is recorded at Reel No. 012736 and Frame No. 0550. Subsequently, Galileo Laboratories, Inc. changed its name to Galileo Pharmaceuticals, Inc. which name change is recorded at Reel No. 013805 and Frame No. 0479 and an assignment from the seventh inventor to Galileo Pharmaceuticals, Inc. which assignment is recorded at Reel No. 014303 and Frame No. 0513.

RELATED APPEALS AND INTERFERENCES

Appellants filed a Notice of Appeal for U.S. patent application serial no. 10/017,717 on September 6, 2005. This appeal may be related to, directly affect or be directly affected by or have a bearing on the decision on appeal taken in this application. An Appeal Brief was filed on November 7, 2005.

STATUS OF CLAIMS

Claims 3, 5, 7, 8, 24-32, 39-41 and 48-50 are canceled.

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 are rejected.

This rejection of Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 is appealed. A copy of the Claims on Appeal is provided in Claims Appendix.

STATUS OF AMENDMENTS

Appellants submitted an Amendment Pursuant to 37 C.F.R. §41.33 on November 9, 2005. Appellants submit that the Amendment was proper and timely and requested the Examiner enter the Amendment. Appellants have not received notice of whether the Examiner has entered the Amendment. Irrespective of entry of the Amendment, Appellants wish to proceed with this Appeal.

SUMMARY OF CLAIMED SUBJECT MATTER

The appealed claims are directed to a method for treating and/or ameliorating a symptom of neuronal damage associated with a cerebral ischemic condition in a mammalian subject, comprising administering to the subject an effective amount of a non-alpha tocopherol enriched tocopherol composition, and by said administering, reducing neuronal damage related to said cerebral ischemic condition. See, specification, *e.g.*, page 4, lines 1-4 and Claim 1. The cerebral ischemic condition may also be secondary to an occlusion of the cerebral vasculature and the occlusion is due to a thromboembolus. The cerebral ischemia may be due to a spasm of the coronary vasculature. The cerebral ischemic condition may be secondary to a cessation of cardiac function. The cerebral ischemic condition may be secondary to a cardiopulmonary bypass procedure. The cerebral ischemic condition may be secondary to a hemorrhagic event in the cerebral vasculature. See, specification, *e.g.*, page 4, lines 16-23 and page 7, lines 13-19 and Claims 9-14. They are also directed to the method wherein neuronal damage is neuronal cell death, total cerebral infarct volume, total cerebral ischemic damage, cerebral tissue edema, or cognitive dysfunction. See, specification, *e.g.*, page 11, lines 15-20 and Claims 58-62. Some of these methods employ at least 50% of gamma-, beta-, or delta-tocopherol. See, specification, *e.g.*, page 4, line 24-page 5, line 5 and Claim 63. Some methods employ less than 20% alpha-tocopherol and 65%, 75%, or 80% gamma-tocopherol; less than 20% alpha-tocopherol and 65%, 75%, or 80% beta-tocopherol; or less than 20% alpha-tocopherol and 65%, 75%, or 80% delta-tocopherol. See, specification, *e.g.*, page 11, lines 7-13 and Claims 64-72. Some of these methods employ compositions that are administered orally or parenterally and are pharmaceutical or nutritional compositions. See, specification, *e.g.*, page 5, lines 23-27 and Claims 51-54. Some methods employ compositions comprising of a non-alpha tocopherol in a range of about 1-1000, 1-50, and 10-100 mg per kg body weight of the mammalian subject. See, specification, *e.g.*, page 5, lines 15-21 and Claims 55-57.

The claims are also directed to methods wherein the non-alpha tocopherol is a gamma-, beta-, or delta-tocopherol. See, specification, *e.g.*, page 4, lines 5-14 and Claims 2, 4, and 6. Some of the methods employ compositions comprising at least 60%, 65%, 70%, 75%, 80%,

85%, 90%, 95%, or 98% gamma-tocopherol, at least 50%, 65%, 75%, 90%, 95%, or 98% beta-tocopherol, or at least 50%, 65%, 75%, 90%, 95%, or 98% delta-tocopherol. See, specification, e.g., page 4, line 24-page 5, line 5 and Claims 15-23, 33-38, and 42-47.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 2, 4, 6, 9-23, 33-38, 42-47, and 51-72 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Wechter, W. J., U.S. 2004/0058987.¹
2. Claims 1, 2, 9-23, and 51-66 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over Wechter, W. J., 2004/0029954.
3. Claims 1, 4, 9-14, 33-38, 51-63, and 67-69 stand rejected under U.S.C. §103(a) as allegedly being unpatentable over Kobayashi, et al., Free Radical Research 2000, 32(2), 115-125.
4. Claims 1, 2, 4, 6, 9-23, 33-38, 42-47, and 51-72 stand rejected under U.S.C. §103(a) as allegedly being unpatentable over Chabrier de Lassauniere, et al., U.S. Patent 6,297,287.

ARGUMENT

1. Rejection under 35 U.S.C. §102(e) over Wechter US 2004/0058987

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47, and 51-72 stand rejected under 35 U.S.C. §102(e) over Wechter US 2004/0058987 (the ‘987 Wechter publication). Appellants hereby reiterate their arguments over this rejection that were originally presented together with the Amendment and Reply under 37 C.F.R. §1.111 filed on August 12, 2004 and again presented together with the Amendment and Reply under 37 C.F.R. §1.114 filed on February 9, 2005.

a. The Wechter ‘987 publication is not an effective prior art reference

In order to qualify as a prior art reference under 35 U.S.C. §102(e), the relied upon sections of the reference patent or patent publication must have an effective filing date which is earlier than the effective filing date of the application under examination. MPEP § 706.02(a). To sustain a rejection under 35 U.S.C. §102(e), the invention must have been described in application for patent by another filed in the U.S. (or in an international patent application designating the U.S. under 35 U.S.C. §351(a)) before the invention by the Appellants. Appellants contend that the effective filing date of the instant application is before the effective filing date of the '987 Wechter publication and as such, the '987 Wechter publication does not qualify as a prior art reference.

b. Summary of the Wechter '987 publication as to its effective filing date

The '987 Wechter publication was filed as a continuation application on September 12, 2003. It copied, in part, the claims of Appellants' instant application which published October 3, 2002. A comparison table is provided below:

Appellants' Original Claim filed 12/14/2002	Claim in Wechter 2004/0058987 filed 9/12/2003
1	1
2	2
3 ²	3
8 ³	4
9	5

¹ We believe that the rejection of Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 under 35 U.S.C. §102(e) as being anticipated by Wechter, W. J., U.S. 2004/0058986 was withdrawn according to the Office Action dated May 25, 2005.

² Canceled by previous amendment.

³ Canceled by previous amendment; note that 6-hydroxy-2,7,8-trimethylchroman-2-propanoic acid (LLU- α) is the same as gamma-CEHC (see, e.g., page 14, lines 19-25 of the instant specification).

Appellants' Original Claim filed 12/14/2002	Claim in Wechter 2004/0058987 filed 9/12/2003
10	6
15	7
16	8
17	9
18	10
22	13
51	15
52	16
53	17
54	18

The specification of the '987 Wechter publication describes the use of gamma-tocopherol and its metabolite LLU- α (gamma-CEHC) to treat a number of conditions: "high blood pressure, thromboembolic disease, cardiovascular disease, cancer, natriuretic disease, the formation of neuropathological lesions and a reduced immune system response..." (Paragraph [0008]); "producing a natriuretic effect" (Paragraph [0009]); "cardiovascular diseases such as ischemia, angina, edematous conditions, atherosclerosis, LDL-oxidation, adhesion of monocytes to endothelial cells, foam cell formation, fatty-streak development, platelet adherence, platelet aggregation, smooth muscle cell proliferation, and reperfusion injury....treat and prevent cancers such as lung cancer, prostate cancer, breast cancer, and colon cancer..." (Paragraph [0011]); "treatment and prevention of natriuretic diseases, such as hypertension, high blood pressure, ischemia, angina pectoris, congestive heart failure, cirrhosis of the liver, nephritic syndrome, ineffective renal perfusion or ineffective glomerular filtration....neurological diseases including hyporeflexia, ophthalmoplegia, and axonal dystrophy... improve a subject's immune system response, reduce the production of free radicals..." (Paragraph [0012]); "natriuretic diseases [meaning] disease associated with abnormal excretion of sodium from the body...hypertension, high blood pressure, ischemia, angina pectoris, congestive heart failure, cirrhosis of the liver,

nephritic syndrome, ineffective renal perfusion, and ineffective glomerular filtration" (Paragraph [0018]).

While, as exemplified above, the specification of the '987 Wechter publication describes the use of gamma-tocopherol for treating a variety of diseases, nowhere in this specification *nor in any of the Wechter priority applications* is the term "cerebral ischemic condition" used by Wechter. Furthermore, the specification of '987 Wechter publication does not describe a method for treating and/or ameliorating a symptom of neuronal damage associated with a cerebral ischemic condition in a mammalian subject by administering an effective amount of a non-alpha tocopherol enriched tocopherol composition. Comparison with parent application(s) reveals that the claims directed to such treatment were added in the present application as of its filing date of September 12, 2003 and that most of these claims⁴ appear to be copied from Appellants' previously published applications.⁵

c. The claims added on September 12, 2003 to the '987 Wechter were new matter

As stated above, in order to sustain a rejection under 35 U.S.C. §102(e), the invention must have been described in application for patent by another filed in the U.S. (or in an international patent application designating the U.S. under 35 U.S.C. §351(a)) before the invention by the Appellants.

Although the '987 Wechter publication claims priority to earlier filed continuation applications, Appellants maintain for the reasons noted at length above that the specification on which the '987 Wechter publication is based (which is identical to his priority cases) does not

⁴ Wechter's claims 11, 12, 14 and 19 recite variations or slightly different (but overlapping) ranges of claims presented by the instant application.

⁵ The instant application published as U.S. Publication 2004/0143049 on October 3, 2002; a corresponding PCT application published as WO 0247680 on June 20, 2002.

support the claims filed therein. The claims filed with the September 12, 2003 was new matter. Accordingly, the claims and the subject matter thereof cannot derive benefit of the earlier filing date(s). Appellants urge that the Honorable Board of Patent Appeals and Interferences accord an effective filing date for these claims in the '987 publication of September 12, 2003.

The effective filing date of the claims in the '987 Wechter publication should be September 12, 2003. This is *later than* both the filing date and the priority dates of the appealed claims in the present application. Accordingly, the subject matter of the claims of the '987 Wechter publication do not anticipate the appealed claims.

d. Rejection under 35 U.S.C. §102(e) over the '987 Wechter publication is improper

In view of the above, the rejection of Claims 1, 2, 4, 6, 9-23, 33-38, 42-47, and 51-72 under 35 U.S.C. §102(e) over the '987 Wechter publication is improper. Withdrawal of this rejection by the Honorable Board of Patent Appeals and Interferences is requested.

2. Rejection under 35 U.S.C. §103 over U.S. 2004/0029954

Claims 1, 2, 9-23 and 51-66 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over Wechter, W.J., U.S. 2004/0029954 (the '954 Wechter publication). Appellants hereby reiterate their arguments over this rejection that were originally presented together with the Amendment and Reply under 37 C.F.R. §1.111 filed on August 12, 2004 and again presented together with the Amendment and Reply under 37 C.F.R. §1.114 filed on February 9, 2005.

a. Summary of the '954 Wechter publication

The '954 Wechter publication was filed on February 21, 2003 and claims priority via a series of continuation applications to U.S. Serial No. 09/215,608 filed on December 17, 1998 (collectively, the Wechter priority applications). Appellants submit that, except for the claims,

the specification of the '954 Wechter publication is essentially identical to that of the '987 Wechter publication described above. The '954 Wechter publication provides a whole "laundry list" of maladies. However, neither the '954 Wechter publication nor any of the Wechter priority applications describe or support the subject matter of the claims set forth in the application as filed on February 21, 2003 (and published as the '954 Wechter publication), which form the basis for the Examiner's rejection under this section.

It is the Examiner's position that the claims of the '954 Wechter publication "directed to methods of treating or preventing any ischemic condition comprising administering a composition comprising tocopherols, at least 50% of which being gamma-tocopherol" render the Appellants' claimed invention obvious.

b. The '954 Wechter publication is not an effective prior art reference

Although the '954 Wechter publication claims priority to earlier filed continuation applications, Appellants maintain that the specification on which the '954 Wechter publication is based (which is identical to his priority cases) does not support the claims filed therein. Accordingly, the claims and the subject matter thereof cannot derive benefit of the earlier filing date(s). Appellants urge that the Honorable Board of Patent Appeals and Interferences accord an effective filing date for these claims in the '954 publication of February 21, 2003.

As stated above, the subject matter of the '954 Wechter publication that the Examiner cites against the Appellants' claimed invention is not supported by the specification and therefore does not derive the benefit of the earlier filing date(s). Specifically, the filing date of '954 Wechter publication is *later than* both the filing date and the priority dates of the Appellants' instant application, the cited subject matter of '954 Wechter publication cannot render obvious the Appellants' claimed invention.

c. The '954 Wechter publication does not render obvious the claimed subject matter of the instant application.

The subject matter of the specification of '954 Wechter publication is described in the previous section. To reiterate, '954 Wechter publication describes the use of gamma-tocopherol, to treat a number of conditions: "high blood pressure, thromboembolic disease, cardiovascular disease, cancer, natriuretic disease, the formation of neuropathological lesions and a reduced immune system response..." (Paragraph [0008]); "producing a natriuretic effect" (Paragraph [0009]); "cardiovascular diseases such as ischemia, angina, edematous conditions, atherosclerosis, LDL-oxidation, adhesion of monocytes to endothelial cells, foam cell formation, fatty-streak development, platelet adherence, platelet aggregation, smooth muscle cell proliferation, and reperfusion injury....treat and prevent cancers such as lung cancer, prostate cancer, breast cancer, and colon cancer" (Paragraph [0011]); "treatment and prevention of natriuretic diseases, such as hypertension, high blood pressure, ischemia, angina pectoris, congestive heart failure, cirrhosis of the liver, nephritic syndrome, ineffective renal perfusion or ineffective glomerular filtration....neurological diseases including hyporeflexia, ophthalmoplegia, and axonal dystrophy... improve a subject's immune system response, reduce the production of free radicals..." (Paragraph [0012]); "natriuretic diseases [meaning] disease associated with abnormal excretion of sodium from the body...hypertension, high blood pressure, ischemia, angina pectoris, congestive heart failure, cirrhosis of the liver, nephritic syndrome, ineffective renal perfusion, and ineffective glomerular filtration" (Paragraph [0018]).

The '954 Wechter publication might suggest the use of gamma-tocopherol for a whole plethora of indications, these indications would not fall into the category of cerebral ischemic conditions. Further, there is nothing in the reference that would suggest that its teachings of the treatment of the various enumerated disease states might also be applicable to treating non-cardiovascular tissue ischemia.

Since the reference neither shows nor suggests methods of treating cerebral ischemia, along the lines of the Appellants' claimed invention, the '954 Wechter publication does not render the claimed invention obvious.

In view of the above, the rejection of claims 1, 2, 4, 6, 9-23, 33-38, 42-47, and 51-72 under 35 U.S.C. §103 over the '954 Wechter publication is improper. Withdrawal of this rejection by the Honorable Board of Patent Appeals and Interferences is requested.

3. Rejection under 35 U.S.C. §103(a) over Kobayashi et al.

Claims 1, 4, 9-14, 33-38, 51-63 and 67-69 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kobayashi et al., Free Radical Research (2000), 32(2), 115-125 (Kobayashi).

a. Standard for *prima facie* case of obviousness

To establish a *prima facie* case of obviousness, the Office has the burden of showing the following three criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP 2143). Appellants submit that the office has not met its burden.

b. Summary of Kobayashi

Kobayashi explains that antioxidants and herbal extracts protect HT-4 neuronal cells *in vitro* against glutamate-induced cytotoxicity. As explained below, while the article may demonstrate *in vitro* use of tocopherol derivatives as one of the several antioxidants to protect

HT-4 cells from glutamate-induced cytotoxicity, it does not teach the method administering non-alpha tocopherols for the treatment and prevention of cerebral ischemia in a mammalian subject. Kobayashi also specifies that while a wide range of antioxidants are effective *in vitro*, the doses required vary for each antioxidant and the concentrations used in the model system may not be extrapolated to the *in vivo* situation. Kobayashi only demonstrates that a wide variety of antioxidants inhibit glutamate-induced cytotoxicity in HT-4 neuronal cells *in vitro*.

c. Kobayashi does not render obvious the claimed subject matter of the instant application.

Kobayashi evaluates the *in vitro* ability of a wide variety of antioxidants, including tocopherol analogs, flavonoids, thiol-based antioxidants, and herbal extracts to protect neuronal cells against glutamate-induced cytotoxicity. While Kobayashi teaches *in vitro* use of tocopherol analogs among several other antioxidants, it does not teach a method for treating a mammal with cerebral ischemic condition with a non-alpha tocopherol enriched tocopherol composition. Thus, there is no motivation for one skilled in the art to use Kobayashi's teachings to arrive at Appellants' claimed invention.

Since Kobayashi does not suggest nor motivate any methods for treating cerebral ischemic conditions in a mammalian subject, as currently claimed, it cannot be said to render the instant invention obvious.

In view of the above, the rejection of claims 1, 4, 9-14, 33-38, 51-63 and 67-69 under 35 U.S.C. §103 (a) over Kobayashi is improper. Withdrawal of this rejection by the Honorable Board of Patent Appeals and Interferences is requested.

4. Rejection under 35 U.S.C. §103(a) over Chabrier et al., U.S. 5,297,281

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Chabrier de Lassauniere et al., U.S. Patent 6,297,281 (Chabrier).

a. Standard for *prima facie* case of obviousness

To establish a *prima facie* case of obviousness, the Office must show the following three criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP 2143). Appellants submit that the office has not met its burden.

b. Summary of Chabrier

The invention in Chabrier is "...a pharmaceutical composition comprising, as active ingredient, at least one substance inhibiting NO synthase and at least one substance trapping reactive forms of oxygen." Chabrier, col. 1, lines 7-11. The invention in Charbrier is useful for treating "...cardiovascular and cerebrovascular disorders..." (col. 1; line 20); "...disorders of the central or peripheral nervous system..." (col. 1, line 25); "...proliferative and inflammatory disorders..." (col. 1, line 37); "...diarrhea, vomiting..." (col. 1, line 44); "radioactive irradiation, solar radiation (UVA, UVB); organ transplants; autoimmune and viral diseases..." (col. 1, lines 45-47); "...cancer; and all pathological conditions characterised by the production or dysfunction of nitrogen monoxide and/or reactive forms of oxygen." (col. 1, lines 51-54).

Chabrier also emphasizes on the advantage of the invention as follows.

The advantage of this combination is to reduce considerably the doses of each of the active ingredients and thus to reduce considerably their undesirable effects whilst gaining therapeutic efficacy.

Chabrier, col. 2, lines 17-20.

c. Chabrier does not render obvious the claimed subject matter of the instant application.

Chabrier teaches administration of a dual active agent composition comprising a NO synthase inhibitor and a trapper of oxygen reactive forms to treat a plethora of diseases.

Appellants submit that their invention is directed to a method that employs an effective amount of a composition having a non-alpha tocopherol enriched tocopherol composition. This is clarified in Appellants' Amendment Pursuant to 37 CFR §41.33 filed on November 9, 2005.

Chabrier does not provide any motivation to remove the NO synthase inhibitor and use *only* non-alpha tocopherol enriched tocopherol composition for treating cerebral ischemic conditions. Thus, Chabrier does not render the instant invention obvious.

In view of the above, the rejection of claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 U.S.C. §103 (a) over Chabrier is improper. Withdrawal of this rejection by the Honorable Board of Patent Appeals and Interferences is requested.

CONCLUSION

The rejection of claims imposed by the Examiner should be reversed and the application should be returned to the Examiner so that the Examiner may issue a Notice of Allowance.

Appellants note that the claims of the application also remain rejected under the judicially created doctrine of obviousness-type double patenting over co-pending application USSN:

10/017,717. Upon allowance of the instant application, Appellants will submit a terminal disclaimer to obviate the rejection.

Respectfully submitted,

Date November 23, 2005

By Lorna L. Tanner

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CLAIMS APPENDIX

Claims on Appeal

The following listing of claims does not encompass the amendments requested in the Amendment Pursuant to 37 C.F.R. §41.33 filed on November 9, 2005.

Claim 1 (Previously presented) A method for treating and/or ameliorating a symptom of neuronal damage associated with a cerebral ischemic condition in a mammalian subject, comprising administering to the subject an effective amount of a non-alpha tocopherol enriched tocopherol composition, and by said administering, reducing neuronal damage related to said cerebral ischemic condition.

Claim 2 (Original) The method of claim 1 wherein the non-alpha tocopherol enriched tocopherol composition is a gamma-tocopherol enriched tocopherol composition.

Claim 3 (Canceled)

Claim 4 (Original) The method of claim 1 wherein the non-alpha tocopherol enriched tocopherol composition is a beta-tocopherol enriched tocopherol composition.

Claim 5 (Canceled)

Claim 6 (Original) The method of claim 1 wherein the non-alpha tocopherol enriched tocopherol composition is a delta-tocopherol enriched tocopherol composition.

Claim 7 (Canceled)

Claim 8 (Canceled)

Claim 9 (Original) The method of claim 1 wherein the cerebral ischemic condition is secondary to an occlusion of the cerebral vasculature.

Claim 10 (Previously presented) The method of claim 9 wherein the occlusion is due to a thromboembolus.

Claim 11 (Original) The method of claim 1 wherein the cerebral ischemia is due to a spasm of the coronary vasculature.

Claim 12 (Original) The method of claim 1 wherein the cerebral ischemic condition is secondary to a cessation of cardiac function.

Claim 13 (Original) The method of claim 1 wherein the cerebral ischemic condition is secondary to a cardiopulmonary bypass procedure.

Claim 14 (Original) The method of claim 1 wherein the cerebral ischemic condition is secondary to a hemorrhagic event in the cerebral vasculature.

Claim 15 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 60% gamma-tocopherol.

Claim 16 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 65% gamma-tocopherol.

Claim 17 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 70% gamma-tocopherol.

Claim 18 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 75% gamma-tocopherol.

Claim 19 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 80% gamma-tocopherol.

Claim 20 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 85% gamma-tocopherol.

Claim 21 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 90% gamma-tocopherol.

Claim 22 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 95% gamma-tocopherol.

Claim 23 (Original) The method of claim 2 wherein said gamma-tocopherol enriched tocopherol composition comprises at least 98% gamma-tocopherol.

Claims 24–32 (Canceled)

Claim 33 (Original) The method of claim 4 wherein said beta-tocopherol enriched tocopherol composition comprises at least 50% beta-tocopherol.

Claim 34 (Original) The method of claim 4 wherein said beta-tocopherol enriched tocopherol composition comprises at least 65% beta-tocopherol.

Claim 35 (Original) The method of claim 4 wherein said beta-tocopherol enriched tocopherol composition comprises at least 75% beta-tocopherol.

Claim 36 (Original) The method of claim 4 wherein said beta-tocopherol enriched tocopherol composition comprises at least 90% beta-tocopherol.

Claim 37 (Original) The method of claim 4 wherein said beta-tocopherol enriched tocopherol composition comprises at least 95% beta-tocopherol.

Claim 38 (Original) The method of claim 4 wherein said beta-tocopherol enriched tocopherol composition comprises at least 98% beta-tocopherol.

Claims 39–41 (Canceled)

Claim 42 (Original) The method of claim 6 wherein said delta-tocopherol enriched tocopherol composition comprises at least 50% delta-tocopherol.

Claim 43 (Original) The method of claim 6 wherein said delta-tocopherol enriched tocopherol composition comprises at least 65% delta-tocopherol.

Claim 44 (Original) The method of claim 6 wherein said delta-tocopherol enriched tocopherol composition comprises at least 75% delta-tocopherol.

Claim 45 (Original) The method of claim 6 wherein said delta-tocopherol enriched tocopherol composition comprises at least 90% delta-tocopherol.

Claim 46 (Original) The method of claim 6 wherein said delta-tocopherol enriched tocopherol composition comprises at least 95% delta-tocopherol.

Claim 47 (Original) The method of claim 6 wherein said delta-tocopherol enriched tocopherol composition comprises at least 98% delta-tocopherol.

Claims 48–50 (Canceled)

Claim 51 (Original) The method of claim 1 wherein said composition is a nutritional composition.

Claim 52 (Original) The method of claim 1 wherein said composition is a pharmaceutical composition.

Claim 53 (Original) The method of claim 1 wherein said composition is administered orally.

Claim 54 (Original) The method of claim 1 wherein said composition is administered parenterally.

Claim 55 (Original) The method of claim 1 wherein said composition comprises a non-alpha tocopherol in a range of 1-1000 mg per kg body weight of said mammalian subject.

Claim 56 (Original) The method of claim 1 wherein said composition comprises a non-alpha tocopherol in a range of 1-50 mg per kg body weight of said mammalian subject.

Claim 57 (Original) The method of claim 1 wherein said composition comprises a non-alpha tocopherol in a range of 10-100 mg per kg body weight of said mammalian subject.

Claim 58 (Previously presented) The method of claim 1, wherein said neuronal damage is neuronal cell death.

Claim 59 (Previously presented) The method of claim 1, wherein said neuronal damage is total cerebral infarct volume.

Claim 60 (Previously presented) The method of claim 1, wherein said neuronal damage is total cerebral ischemic damage.

Claim 61 (Previously presented) The method of claim 1, wherein said neuronal damage is cerebral tissue edema.

Claim 62 (Previously presented) The method of claim 1, wherein said neuronal damage is cognitive dysfunction.

Claim 63 (Previously presented) The method of claim 1, wherein said non-alpha tocopherol is selected from the group consisting of gamma-tocopherol, beta-tocopherol and delta-tocopherol, wherein said non-alpha tocopherol comprises at least 50% of said tocopherol composition.

Claim 64 (Previously presented) The method of claim 63, wherein said non-alpha tocopherol is gamma-tocopherol, which comprises at least 65% of said tocopherol composition, and wherein alpha-tocopherol comprises less than 20% of said tocopherol composition.

Claim 65 (Previously presented) The method of claim 64, wherein the gamma-tocopherol comprises at least 75% of said tocopherol composition.

Claim 66 (Previously presented) The method of claim 64, wherein said gamma-tocopherol comprises at least 80% of said tocopherol composition.

Claim 67 (Previously presented) The method of claim 63 wherein said non-alpha tocopherol is beta-tocopherol, which comprises at least 65% of said tocopherol composition, and wherein alpha-tocopherol comprises less than 20% of said tocopherol composition.

Claim 68 (Previously presented) The method of claim 67, wherein the beta-tocopherol comprises at least 75% of said tocopherol composition.

Claim 69 (Previously presented) The method of claim 67, wherein the beta-tocopherol comprises at least 80% of said tocopherol composition.

Claim 70 (Previously presented) The method of claim 63 wherein said non-alpha tocopherol is delta-tocopherol, which comprises at least 65% of said tocopherol composition, and wherein alpha-tocopherol comprises less than 20% of said tocopherol composition.

Claim 71 (Previously presented) The method of claim 70, wherein the delta-tocopherol comprises at least 75% of said tocopherol composition.

Claim 72 (Previously presented) The method of claim 70, wherein the delta-tocopherol comprises at least 80% of said tocopherol composition.

EVIDENCE APPENDIX

No additional evidence is being submitted with this appeal.

RELATED PROCEEDINGS APPENDIX

No decisions have been rendered by a court or by the Board in the related proceeding mentioned herewith.